III. REMARKS

Claim status

Claims 1, 3-15 17-22 are in the case. Claims 1, 3, 6-7 and 17 have been amended; claims 2 and 4-5 have been canceled.

Specification

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to provide an adequate written description of the invention, and failing to adequately teach how to make and/or use the invention, i.e. failing to provide an enabling disclosure.

Contrary to the statement of the Examiner that the specification only teaches polyclonal antibodies, at page 3, last sentence and at page 5 of the specification, third line from the bottom of the description, it is taught that the invention can to be carried out by the use of mono- and polyclonal antibodies. The production of monoclonals is taught at page 6, first paragraph. For someone skilled in the art it is routine work to produce polyclonal as well as monoclonal antibodies when he is in possession of the antigens.

Furthermore, the claims have been amended to refer to "pancreatic elastases I, II and III (iso-enzymes)" rather than "all known pancreatic elastases" thus bringing them into compliance with the specification.

Claim rejection 35 U.S.C. 112, first paragraph

Claims 1, 3-11 and 17-22 are rejected under 35 U.S.C. 112, first paragraph, for reasons of record, that the specification contains subject matter which was not described in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, and which was not described in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. For the reasons of record, the issue is whether the disclosure describes and supports the ability of the recited peptides to elicit antibodies that bind singly, or in combination, and function for determination of all elastase isoforms in a body fluid sample.

The examiner states that applicant teaches only polyclonal antibodies to particular peptides and provides no description or guidance to any single antibody or monospecific species which functions in the invention to bind to all known elastase iso-enzymes.

Applicant traverses this ground for rejection.

Contrary to the statement of the Examiner that the specification only teaches polyclonal antibodies, at page 3, last sentence of the description, it is taught that the invention can to be carried out by the use of mono- and polyclonal antibodies. For someone skilled in the art it is routine work to produce polyclonal as well as monoclonal antibodies when he is in possession of the antigens.

Furthermore, the claims have been amended to refer to "pancreatic elastases I, II and III (iso-enzymes)" rather than "all known pancreatic elastases".

Concerning the ground for rejection based on the principle that the product itself is required and not a generic statement which defines a genus of products, applicant believes the product is clearly defined by the amended claim 1.

Applicant also believes claim 1 now is commensurate with subject matter that is disclosed in the description.

Concerning the Examiners argument regarding the abstracts of Dr. Weiss, these abstracts is clearly disclose that the antibodies do not bind to porcine enzymes.

Applicant contends is not necessary to describe which anti-peptide antibody binds to which isoform as well as to provide further guidance for useable combinations. Useable combinations are described in the amended claims. Further guidance is not needed for someone skilled in the art.

It is sufficient to know that it is possible to determine the overall content of the pancreatic elastases 1, 2 and 3 by the use of the mentioned anti-peptide antibodies. Someone skilled in the art is able to carry out the invention. The abstracts of Dr. Weiss and Dr. Keim, previously submitted, prove this.

The abstracts further state that the differences and specific function of PA II or PA III are unknown and that this matter as well as the prognostic value needs further evaluation.

This does not mean that the ability for diagnoses according to the invention itself is challenged. This is only the common outlook of a publication which points into the direction further basic research could be carried out to learn more about possibly differences in functions e.g. of the several elastases.

But there is no connection to the claimed subject matter, which relates to a finished invention which doesn't need any further evaluation, because it works as already demonstrated.

In this connection applicant refers to the publications of Dr. Keim where it is shown that chronic pancreatitis in patients was diagnosed (advantageously over the state of the art) by the use of the antibodies according to the invention. The ability for diagnoses by testing PAII and PAIII as claimed in the invention is proven.

Claim Rejections 35 U.S.C. § 112, second paragraph, indefinite

Claims 1, 3-6, and 18-21 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As stated by the examiner, claims 1, 3-5, 20, and 21 are method claims and should clearly set forth the various method steps in a positive, sequential manner using active tense verbs such as mixing, reacting, and detecting.

Applicant has amended the claims to use the active tense.

In claim 4, "the antigen" lacks antecedent basis.

Claim 4 has been cancelled.

In claim 3 and claims dependent thereupon, it is not clear to the examiner how antibodies are obtained "by means of antigens."

The claim has been amended to clarify the meaning.

In claim 6, "the pancreas" lacks antecedent basis.

Applicant believes the examiner has taken the phrase out of context and cannot recognize the need for an antecedent to “the pancreas” as it is clearly “the pancreas of a patient”.

The examiner rejects claim 18 as indefinite in that the claim fails to further limit the subject matter of a previous claim. As stated by the examiner, it sets forth an intended use but fails to point out what components are included or excluded by the claim language.

Applicant traverses this ground for rejection. The limitation in this claim not appearing in the claim it depends upon is the recitation of “two different” antibodies.

In claim 19, as stated by the examiner the interrelationships of the components are not clear, e.g. it is not clear if hemocyanin is a carrier substance.

Applicant traverses this ground for rejection. The claim clearly sets forth the coupling that defines the resultant molecule. Whatever the function of the hemocyanin may be is not relevant.

In claim 20, as stated by the examiner, the interrelationships of the components are not clear, e.g. it is not clear if peptides are sub-units. Applicant believes the peptides are sufficiently defined their ability to function as antigens and, per claim 3, are complete elastases or their subunits.

It is not clear to the examiner what is intended by "myeoloma cells" or "hybridoma cells which are cultivated in cell lines."

Applicant is not sure of where the examiner believes the lack of clarity exists.

Myeloma cells are white blood cells also known as plasma cells and are a type of B cell, responsible for the production of antibodies in humans and other vertebrates. They are produced in the bone marrow and populate, and are transported through, the lymphatic system.

Hybridoma cells are hybrid cells lines formed by fusing a specific antibody-producing B lymphocyte with a myeloma cell that is selected for its ability to grow in tissue culture.

Claim Rejection 35 U.S.C. § 102(b)

Claims 1, 3-8, 10, 12-15, 17, 18, 21, and 22 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Sziegoleit et al. (Clin. Biochem. 22: 79, 1989) in light of the instant disclosure.

The Declaration of Dr. Hans-Werner Heinrich refutes the examiner's contentions and negates the basis for this rejection.

Dr. Heinrich readily distinguishes Sziegoleit et al.

Applicant encloses with this response four absracts of Dr. Weiss's groups work in this area and dated as early as June 6, 2006 which show that porcine pancreatin was not cross-reactive, and that elastase I is not expressed in the adult human pancreas.

Thus, the only conclusion that can be drawn from Dr. Weiss' work is that there was no elastase I to bind to in the sample, not that the antibodies would not bind to elastase I if elastase I were present.

The Commissioner is hereby authorized to charge payment for any fees associated with this communication or credit any over payment to Deposit Account No. 14-1263.

Respectfully submitted,

NORRIS McLAUGHLIN & MARCUS, P.A.

By
Serle Ian Mosoff
Attorney for Applicant(s)
Reg. No. 25,900

875 Third Avenue - 8th Floor
New York, New York 10022
Phone: (212) 808-0700
Fax: (212) 808-0844